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K960490

31 January, 1996

MAY - 3 1996

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PRODUCT NAMES

Device name: AS/3TM Compact Airway Module M-CAiOV

Common name: Airway gas, pressure and volume measurement device

DESCRIPTION OF THE DEVICE

The AS/3TM Compact Airway Module M-CAiOV is a part of the modular anesthesia monitoring system AS/3TM. It measures carbon dioxide (CO₂), nitrous oxide (N₂O), oxygen (O₂) and anesthetic agent concentration (AA) of respiratory gases. The Airway Module also identifies anesthetic agent (ID) and measures airway pressure and volume (pV).

The sampled gases are analyzed by an infrared photometer and a paramagnetic oxygen sensor. Respiratory rate is derived from the CO₂ signal. The anesthetic agents (halothane, enflurane, isoflurane, desflurane and sevoflurane) are identified from the sampled gases with infrared technique. Airway gas flow is measured with the aid of a pneumotachometer type transducer and airway pressure is measured from the same adapter by means of a pressure transducer.

INTENDED USE

The AS/3TM Compact Airway Module M-CAiOV is intended to be used in the Datex AS/3TM Anesthesia Monitor or in the AS/3TM Compact Monitor in anesthesia department, including operation rooms (OR) and post-anesthesia care units (PACU) etc.

SUBSTANTIAL EQUIVALENCE

In terms of overall functions and parameters measured, the AS/3TM Compact Airway Module connected to the AS/3TM Frame is substantially equivalent in safety and effectiveness to Datex AS/3TM Airway Module G-AiOV.

All measured parameters are the same as in previously approved G-AiOV Airway Module. The sensors are redesigned. CO₂ and N₂O are measured with infrared absorption with the same wavelengths as before. Anesthetic agents are measured with the same technique but

at a different wavelength as earlier. Oxygen sensor measurement principle is the same as before, only the sensor is redesigned. Spirometry measurement principle is the same as earlier with the same pressure sensors.

Both gas measurement and spirometry measurement accuracy's were verified with both Compact Airway Module M-CAiOV and Airway Module G-AiOV at the same time. The results showed that both performed within specifications and the results were substantially equivalent.